

CLAIMS

1. A method of treating a tumor comprising:

5 providing a tissue biopsy and treatment apparatus for detecting and treating a tumor, the apparatus comprising an elongated delivery device including a lumen, the elongated delivery device being maneuverable in tissue; a sensor array deployable from the elongated member, the sensor array including a plurality of resilient members, at least one of the plurality of resilient members being positionable in the elongated delivery device in a compacted state and deployable with curvature into tissue from the elongated delivery device in a deployed state, at least one of the plurality of resilient members including at least one of a sensor, a tissue piercing distal end or a lumen, the sensor array having a geometric configuration adapted to volumetrically sample tissue at a tissue site to differentiate or identify tissue at the tissue site; and at least one energy delivery device coupled to one of the sensor array, at least one of the plurality of resilient members or the elongated delivery device;

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20 introducing the apparatus into a target tissue site;
distinguishing a tissue type utilizing the sensor array;
positioning the energy delivery device utilizing tissue type information derived from the sensor array to ablate a tumor volume;
delivering energy from the energy delivery device to ablate or necrose at least a portion of the tumor volume; and
25 determining an amount of tumor volume ablation utilizing the sensor array.

Sub 2. The method of claim 1, further comprising:
monitoring a tissue volume in the target tissue site.

3. The method of claim 2, wherein the apparatus includes logic resources coupled to at least one of the sensor, the energy delivery device or a power source coupled to the energy delivery device, the method further comprising:

adjusting one of a power, current, power duty cycle or fluid flow response to an input from the sensor array.

10 *Sub 6* 4. The method of claim 3, wherein the input is at least one of a temperature, an impedance, an optical absorbance, an optical reflectance or a pH.

15 5. The method of claim 3, wherein the logic resources include at least one of a processor, a microprocessor, a software module, a fuzzy logic module, a temperature compensation module, or a database.

20 6. The method of claim 2, wherein the tissue volume includes at least a first tissue volume and a second tissue volume.

25 7. The method of claim 6, wherein the at least a first tissue volume is in closer proximity to the energy delivery device than the second tissue volume.

8. The method of claim 6, wherein the first tissue volume is within a tumor volume and the second tissue volume is outside of the tumor volume.

9. The method of claim 1, further comprising:
comparing a first tissue volume to a second tissue volume.

10. The method of claim 9, wherein the first tissue volume is in substantial proximity to a first portion of the sensor array and the second tissue volume is in substantial proximity to a second portion of the sensor array.

11. The method of claim 10, further comprising:
positioning the first portion of the sensor array in the first tissue volume and the second portion of the sensor array in the second tissue volume.

12. The method of claim 9, further comprising:
comparing a property of the first tissue volume to a property of the second tissue volume.

13. The method of claim 13, wherein the tissue property includes at least one of a physiologic property, a metabolic property, a genetic property, a thermal property, a temperature, an electrical property, an impedance, an optical property, an absorbance, a reflectance, a dimensional property or a pH.

14. The method of claim 9, wherein the first tissue volume is within a tumor volume and the second tissue volume is outside of the tumor volume.

15. The method of claim 9, further comprising
differentiating between a first tissue type in the first tissue volume and a second tissue type in the second tissue volume.

16. The method of claim 10, wherein at least the first sensor array portion is positioned in closer proximity to the energy delivery device than the second sensor array portion.

5 17. The method of claim 10, wherein at least the first sensor array portion includes a first plurality of sensors and the second sensor array portion includes a second plurality of sensors.

10 18. The method of claim 1, further comprising:
locating a tumor volume within the target tissue site utilizing the sensor array.

15 19. The method of claim 18, further comprising:
positioning the sensor array to detect one of the tumor volume or a boundary of the tumor volume.

20 20. The method of claim 18, further comprising:
positioning the energy delivery device within the located tumor volume to controllably ablate at least a portion of the target volume.

21. The method of claim 1, further comprising:
identifying a tumor boundary utilizing the sensor array.

25 22. The method of claim 21, further comprising:
positioning the energy delivery device relative to the tumor boundary to controllably ablate at least a portion of a tumor volume.

23. The method of claim 1, further comprising:

determining an amount of tissue necrosis, coagulation, or injury
utilizing the sensor array.

5 24. The method of claim 1, further comprising:
determining a treatment end point utilizing the sensor array.

10 25. The method of claim 1, further comprising
determining a healthy tissue ablative margin responsive to an input
from the sensor array.

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15 26. The method of claim 25, wherein the input is at least one of
an optical input, a spectra, an absorbance spectra, a reflectance spectra, a
change in reflectance, a change in absorbance, a tissue type or a tissue
property.

20 27. The method of claim 25, further comprising:
positioning the energy delivery device within the a tissue volume
defined by the healthy tissue margin;
delivering energy from the energy delivery device to ablate or
necrose tissue in the tissue volume defined by the health tissue margin.

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28. The method of claim 25, wherein the healthy tissue margin is
determined using logic resources coupled to the sensor array.

25 29. The method of claim 25, wherein the logic resources are
electronically coupled to a power source coupled to the energy delivery
device.

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30. The method of claim 25, wherein the logic resources include at least one of a processor, a microprocessor, a software module, a fuzzy logic module, a database, a histological database, a tumor database, or a database of prior ablations.

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31. The method of claim 30, further comprising:
comparing an input from the sensor array to the database.

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32. The method of claim 1, further comprising:
identifying at least one of a tissue type or a tissue property utilizing the sensor array.

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33. The method of claim 32, wherein the tissue identification is determined using logic resources coupled to the sensor array.

34. The method of claim 33, wherein the logic resources are electronically coupled to a power source coupled to the energy delivery device.

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35. The method of claim 33, wherein the logic resources include at least one of a processor, a microprocessor, a software module, a fuzzy logic module, a database, a histological database, a tissue database or a tumor database.

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36. The method of claim 36, further comprising:
comparing an input from the sensor array to the database.

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37. The method of claim 32, wherein the tissue type is one of a cancer, a metastatic cancer, a cyst, a tumor a coagulated tissue, an injured tissue, a lysed tissue or a necrosed tissue.

5 ~~38.~~ The method of claim 32, wherein the tissue property includes at least one of a physiologic property, a metabolic property, a genetic property, a thermal property, a temperature, an electrical property, an impedance, an optical property, an absorbance, a reflectance, a hemoglobin saturation, a dimensional property or a pH.

10 Sub B 6 39. The method of claim 32, further comprising:
making a treatment decision based on information derived from a tissue identification or a tissue property.

15 40. The method of claim 32, further comprising:
making one of a diagnosis or differential diagnosis based on the tissue property.

20 41. The method of claim 32, further comprising
making a differential diagnosis based on at least two tissue properties.

25 42. The method of claim 39, wherein the treatment decision is at least one of a resection, a biopsy, an ablation, an energy delivery, an amount of energy delivery, an energy delivery duty cycle, a drug delivery, an amount of drug delivery or a chemotherapeutic agent delivery.

43. The method of claim 32, further comprising:

titrating a tissue treatment based on information derived from a tissue identification or a tissue property.

5 44. The method of claim 39, wherein the treatment is at least one of a resection, an ablation, an energy delivery, a drug delivery or a chemotherapeutic agent delivery.

20 45. The method of claim 32, wherein the tissue property includes at least one of a physiologic property, a metabolic property, a thermal property, a temperature, an electrical property, an impedance, an optical property, an absorbance, a reflectance, a dimensional property or a pH.

15 46. The method of claim 1, further comprising:
deploying the sensor array within a selectable tissue volume.

20 47. The method of claim 1, further comprising:
obtaining a baseline tissue property measurement of the target tissue utilizing the sensor array.

25 48. The method of claim 47, further comprising:
comparing the baseline property measurement to a second tissue property measurement made during or after the delivery of energy to the target tissue.

30 49. The method of claim 48, further comprising:
adjusting an energy delivery parameter responsive to the comparison of the baseline measurement to the second measurement.

50. The method of claim 49 further comprising:

~~adjusting the energy delivery parameter to enhance at least one of a tissue ablation time, a tissue ablation volume or a thermal injury effect.~~

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51. The method of claim 49 further comprising:
adjusting the energy delivery parameter to compensate for hysteresis, thermal hysteresis, electrical hysteresis, tissue desiccation, cell lysis or protein denaturation.

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52. The method of claim 49, wherein the energy delivery parameter is one of a power level, a power duty cycle, a current, a fluid flow rate, or an electrolytic fluid flow rate.

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53. The method of claim 48, further comprising:
making an treatment endpoint decision responsive to the comparison of the baseline measurement to the second measurement.

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54. The method of claim 49, wherein the adjustment is determined using logic resources coupled to the sensor array.

55. The method of claim 49, wherein the logic resources are electronically coupled to a power source coupled to the energy delivery device.

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56. The method of claim 49, wherein the logic resources include at least one of a processor, a microprocessor, a software module, a fuzzy logic module, a database, a histological database, a tissue database or a tumor database.

57. The method of claim 1, further comprising:

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deploying a marking agent; and
marking at least one of a tumor volume, a tumor surface, an ablated
tissue volume, a hyperthermic tissue volume, or an injured tissue volume.

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58. The method of claim 57, wherein tissue marking agent is one
of a tumor marker, a temperature sensitive marker, a fluorescent marker, a
radioactive marker, an antibody, an antibody-coupled marker, a liposome, a
liposome-coupled marker, an antibody-coated liposome, a microsphere or a
chemotherapeutic agent.

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59. The method of claim 57, wherein tissue marking agent
includes a first marking agent and a second marking agent.

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60. The method of claim 59, wherein the first marking agent is
configured to mark a first tissue condition and the second marking agent is
configured to mark a second tissue condition.

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61. The method of claim 59, wherein the first marking agent is
configured to mark a tumor condition and the second marking agent is
configured to mark a thermal condition.

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62. The method of claim 59, wherein the first marking agent is
configured to mark a first tissue temperature and the second marking agent
is configured to mark a second tissue a temperature.

63. The method of claim 57, wherein the marking agent is
configured to enhance the delivery of energy to a least a portion of the
tumor volume, the method further comprising:

enhancing the delivery of energy to at least a portion of the tumor
volume.

5 64. The method of claim 63, wherein the at least a portion of the
tumor volume is selectable.

10 65. The method of claim 57, wherein the marking agent is
configured to enhance the amount of thermal injury to a least a portion of
the tumor volume, the method further comprising:
enhancing the thermal injury to at least a portion of the tumor
volume.

15 66. The method of claim 65, wherein the at least a portion of the
tumor volume is selectable.

20 67. The method of claim 57, wherein the sensor array is
configured to detect a marking agent.

25 68. The method of claim 67, wherein the sensor array is
configured
to obtain one of an improved resolution or a sensitivity.

69. The method of claim 57, further comprising
a source of marking agent fluidically coupled to the elongated
25 delivery device, the method further comprising:
infusing the marking agent into the target tissue site.

70. The method of claim 57, wherein the plurality of marking
agents includes a first marking agent coupled to a marking agent carrier,

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wherein the marking agent carrier is configured to release the first marking agent at a selectable temperature, the method further comprising:
releasing the marking agent in the target tissue site at a selectable temperature.

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71. The method of claim 70, further comprising:
delivering energy from the energy delivery device to release the marking agent.

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72. The method of claim 70, wherein the selectable temperature is in the range of about 40° C to about 60° C.

73. The method of claim 70, wherein the selectable temperature is in the range of about 45° C to about 55° C.

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74. The method of claim 1, wherein the geometric configuration is configured to detect one of a boundary or a volume of a tumor as at least a portion of the sensor array is advanced into a target tissue site.

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75. The method of claim 1, wherein the energy delivery device is one of an RF electrode, a monopolar electrode or a bipolar electrode.

76. The method of claim 1, wherein a source of RF energy is coupled to the RF electrode.

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77. The method of claim 1, wherein the sensor is one of an optical sensor, a photomultiplier, an optical fiber, a ccd, a temperature sensor or a chemical sensor.

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78. The method of claim 1, wherein the geometric configuration is substantially one of a hemisphere, sphere, oval, cone, pyramidal, a polyhedron or a tetrahedron.

5 ~~79.~~ The method of claim 1, wherein at least one of the first or second resilient members is configured to have a changing direction of travel in tissue when advanced from the elongated delivery device to a selected tissue site.

10 80. The method of claim 79, wherein at least the first resilient member has a first direction of travel and the second resilient member has a second direction of travel.

15 81. The method of claim 79, wherein at least one of the first or second resilient members has at least one of an elastic modulus, a bending modulus, a taper, a memory or a glass transition temperature sufficient to produce a changing direction of travel in response to a force applied by tissue.

20 ~~82.~~ Sub B6 The method of claim 1, wherein the sensor array is configured to differentiate tissue during an energy delivery interval, a tissue desiccation condition, a tissue charring condition or a tissue vaporization condition.

25 83. The method of claim 1, wherein at least one of the resilient members includes an infusion lumen and at least of the resilient members or the energy delivery device includes an infusion port, the method further comprising:
infusing a fluid into the target tissue.

5 84. The method of claim 83, wherein the fluid is one of an electrolytic solution, an electrical conductivity enhancing solution, a thermally conductivity enhancing solution, an image contrast agent, an RF energy absorption agent or an echogenic solution.

85. The method of claim 1, wherein the at least one sensor is configured to detect a change in a tissue property.

10 86. The method of claim 85, wherein the property includes at least one of a physiologic property, a metabolic property, a thermal property, a temperature, an electrical property, an impedance, an optical property, an absorbance, a reflectance, a dimensional property or a pH.

15 87. The method of claim 1, wherein the sensor array is configured to detect least one of a tissue ablation volume, a tissue thermal volume or tissue hyperthermic volume.

20 88. The method of claim 1, wherein the sensor array is configured to distinguish between cancerous and non-cancerous tissue.

25 89. The method of claim 1, wherein the at least one sensor includes a first sensor and a second sensor.

90. The method of claim 89, wherein the at least one of the first or

the second sensors are positioned at a greater distance with the respect to a longitudinal axis of the elongated delivery device than the at least one energy delivery device.

5 91. The method of claim 90, wherein the greater distance is at least one of a lateral or a longitudinal distance.

10 92. The method of claim 89, wherein at least one of the first or second sensors is an emitter, an electromagnetic emitter, an acoustical emitter, an optical emitter, a laser or an LED.

15 93. The method of claim 92, wherein the emitter is substantially positioned within a volume defined by the sensor array.

 94. The method of claim 93, wherein the emitter is substantially positioned within a volume defined by the sensor array.

20 95. The method of claim 92, wherein the emitter emits a reference signal and a probe signal.

 96. The method of claim 95, wherein the at least one sensor includes a third sensor adapted to detect the reference signal.

25 97. The method of claim 95, further comprising:
 employing the reference signal to compensate for a change in a tissue condition at the tissue site, hysteresis, thermal hysteresis, or optical hysteresis.

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98. The method of claim 96, wherein the third sensor is positioned substantially adjacent or in proximity to the emitter.

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99. The method of claim 92, wherein the emitter is configured to electromagnetic energy over a selectable frequency range.

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The method of claim 1, wherein the sensor array includes a third and a fourth resilient member.

100. The method of claim 1, wherein the sensor array includes a third and a fourth resilient member.

101. A method of treating a tumor comprising:
providing a tissue biopsy and treatment apparatus for detecting and
treating a tumor, the apparatus comprising an elongated delivery device
including a lumen, the elongated delivery device being maneuverable in
tissue; a sensor array deployable from the elongated member, the sensor
array including a plurality of resilient members, at least one of the plurality
of resilient members being positionable in the elongated delivery device in a
compacted state and deployable with curvature into tissue from the
elongated delivery device in a deployed state, at least one of the plurality of
resilient members including at least one of a sensor, a tissue piercing distal
end or a lumen, the sensor array having a geometric configuration adapted
to volumetrically sample tissue at a tissue site to differentiate or identify
tissue at the tissue site; and at least one energy delivery device coupled to
one of the sensor array, at least one of the plurality of resilient members or
the elongated delivery device;
introducing the apparatus into a target site;
maneuvering the energy delivery device through tissue responsive to
information derived from the sensor array to ablate a tumor volume;
delivering energy from the energy delivery device to ablate or
necrose at least a portion of the tumor volume; and
determining an amount of tumor volume ablation utilizing the sensor
array.

102. A method of treating a tumor comprising:
providing a tissue biopsy and treatment apparatus for detecting and
treating a tumor, the apparatus having a sensor array positionable at a target
tissue site, the sensor array including at least a first and a second resilient
member, at least one of the first or second resilient members including at

least one of a a sensor, a lumen, a sensor member positionable in the lumen,
an energy delivery or a tissue piercing distal end;

introducing the apparatus into the target tissue site;

positioning the sensor array at the target tissue site;

utilizing the sensor array to make a first measurement of a tissue
parameter at the target site or retrieving a tissue parameter for the target site
from a database of tissue parameters;

delivery energy to the target tissue site;

utilizing the sensor array to make a second measurement of the
tissue parameter during or after an energy delivery interval;

comparing one of the first measurement or the retrieved parameter to
the second measurement; and

determining an amount of injury or ablation of the target tissue
volume utilizing a comparison between one of the first measurement or the
retrieved parameter to the second measurement.

103. The method of claim 102, further comprising:
determining a treatment endpoint.

104. A method of treating a tumor comprising:

providing a tissue biopsy and treatment apparatus for detecting and
treating a tumor, the apparatus comprising an elongated delivery device
including a lumen, the elongated delivery device being maneuverable in
tissue; a sensor array deployable from the elongated member, the sensor
array including a plurality of resilient members, at least one of the plurality
of resilient members being positionable in the elongated delivery device in a
compacted state and deployable with curvature into tissue from the
elongated delivery device in a deployed state, at least one of the plurality of
resilient members including at least one of a sensor, a tissue piercing distal

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end or a lumen, the sensor array having a geometric configuration adapted to volumetrically sample tissue at a tissue site to differentiate or identify tissue at the tissue site; and at least one energy delivery device coupled to one of the sensor array, at least one of the plurality of resilient members or the elongated delivery device;

distinguishing a tissue type utilizing the sensor array means;

positioning the energy delivery device means utilizing tissue type information derived from the sensor array means to ablate a tumor volume;

delivering energy from the energy delivery device to ablate or necrose at least a portion of the tumor volume; and

determining an amount of tumor volume ablation utilizing the sensor array.

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